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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BASQUILL, SEAN M

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

06/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/544,149	Applicant(s) SMITH, FRANCIS X.	
	Examiner Sean Basquill	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants are advised, in future correspondence with the office, to reflect the change of examiners from TRISTAN MAHYERA to SEAN BASQUILL.

Status of the Claims

1. Applicants amended Claim set submitted with the response filed 31 March 2009 has been entered. Claims 3, 6, and 7 have been amended and new Claims 8-15 have been entered.

Claims 1-15 are presented for examination.

Previous Rejections

2. Applicants' arguments, filed 31 March 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 3-6, 8-10, and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,817,277 ("Mowrey-McKee").

Mowrey-McKee teaches a method and solution for disinfecting contact lenses comprising 0.00001-0.1% PHMB and 50-200 ppm (0.005-0.02%) hydrogen peroxide. (Claims 1 & 3). The

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solution is further described as containing additional ingredients such as tonicity agents, surfactants, and viscosity agents (C.3, L.2125), as well as additional microbicides including polyquaternium-1 (also known as POLYQUAD) (C.3, L.5-10) and ophthalmically acceptable chelating agents, including EDTA and citric acid. (C.2, l. 36-59). A specific example of a solution described by Mowrey-McKee contains 0.001% POLYQUAD polyquaternium-1, a quaternary ammonium compound. (C.7, L.29-30). In addition, as put forth in the previous rejection, pages 3-4, Mowrey-McKee describes the use of a buffered solution employing buffers such as tromethamine (C.2, L.16-35), and their use in a container (i.e. a vial) with sufficient amount of solution to cover the lens. (C.3, L.66 - C.4, L.4).

Mowrey-McKee does not specifically the claimed range of peroxide producing agent, although the ranges as claimed and those described in Mowrey-McKee overlap. In addition, Mowrey-McKee does not describe one specific embodiment containing all of the above described elements as claimed.

That being said, however, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR v. Teleflex*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. A.G. Pro*, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (*Id.*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can

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take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR v. Teleflex*, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” *Id.* at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of microbicides such as PHMB and polyquaternium-1, chelating agents such as EDTA from within a prior art disclosure, to arrive at compositions “yielding no more than one would expect from such an arrangement.” Also, while Mowrey-McKee does not disclose the exact values of peroxide as claimed, the disclosed ranges indeed overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. *In re Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

4. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mowrey-McKee as applied to claims 1, 3-6, 8-10, and 12-15, above, and further in view of U.S. Patent 4,758,595 (“Ogunbiyi”)

Mowrey-McKee describes contact lens solutions comprising PHMB, microbicides, surfactants and chelating agents as described above, but does not specifically encompass the polymeric biguanide having between 5-20 repeating units.

Ogunbiyi teaches the biguanide of instant claim 2, with n preferably between 3-8 repeating units. (C.3, L.57-61). Ogunbiyi also indicates the instant cationic polymer is compatible with other antimicrobial agents (C.3, L.34-36), recommending the use of such compositions in ranges of between 0.00001-0.5% (C.7, L.18-25), including n-alkyl dimethyl benzyl ammonium chlorides. (C.7, L.38-45).

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It would have been *prima facie* obvious to one having ordinary skill in the art at the time of the instant invention to have used the biguanide and n-alkyl dimethyl benzyl ammonium chlorides of Ogunbiyi as the cationic polymer and antimicrobial respectively of Mowrey-McKee. One having ordinary skill in the art at the time of the instant invention would have been motivated to do so because, by the express teaching of Ogunbiyi, recognized their suitability as equivalents to the ophthalmically useful polymers and antimicrobials described by Mowrey-McKee. The combination of two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose, is *prima facie* obvious. The idea for combining them flows logically from their having been individually taught in the prior art. MPEP 2144.06.

Double Patenting

5. Claims 1-7 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-6 and 8 of Copending application 11/613,050 for the reasons put forth in the previous action.

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

Conclusion

No Claims are allowable.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill
Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612